

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

DePuy Mitek, Inc.)	
a Massachusetts Corporation)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 04-12457 PBS
)	
Arthrex, Inc.)	
a Delaware Corporation, <i>et al.</i>)	
)	
Defendants.)	
)	

**DEFENDANTS ARTHREX, INC.'S AND PEARSALLS LTD.'S OPPOSITION TO
PLAINTIFF DEPUY MITEK'S MOTION *IN LIMINE* (NO. 1) TO EXCLUDE
EVIDENCE REGARDING CETR TESTING**

Dated: July 24, 2007

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I. INTRODUCTION

DePuy Mitek's motion *in limine* is nothing more than a woefully misleading attempt to prevent Defendants from showing the jury convincing, objective test results that clearly show just how significant an impact coating has on the various pliability and handleability properties of FiberWire suture.

In large part, Defendants will present such objective testing evidence through the testimony of Dr. Norman Gitis, who conducted objective testing on coated and uncoated FiberWire sutures on the following parameters: pliability, knot slippage strength, knot run-down, friction, chatter and tissue drag. DePuy Mitek knows that it cannot challenge Dr. Gitis' credentials or the results of his testing head-on, so instead it devised a way to try and indirectly exclude his tests from the case. DePuy Mitek's strategy is to launch a series of false and unfair attacks on Dr. Mukherjee, Defendants' suture expert, who relied, in part, on Dr. Gitis' testing in forming his opinion that the coating on FiberWire materially affects the basic and novel properties of the '446 patent. Ex. 1 at 25-27.

Notably, DePuy Mitek's motion does not challenge Dr. Mukherjee's qualifications as a suture expert nor does it challenge the validity of Dr. Gitis' test report. Rather, DePuy Mitek cuts-and-pastes together a few portions of Dr. Mukherjee's 582-page deposition transcript, taken completely out-of-context, and tries to create the false impression that Dr. Mukherjee somehow admitted he does not have any opinions as to whether Dr. Gitis' tests show that coating materially affects the tested properties of FiberWire. Not surprisingly, DePuy Mitek omitted from its motion *all of Dr. Mukherjee's testimony that explains exactly what he did rely upon for his opinions* – Dr. Gitis' statistical analysis of the recorded data points.

Contrary to DePuy Mitek's unsupported assertion, Dr. Mukherjee repeatedly explained to DePuy Mitek during his deposition that he certainly *was* an expert in analyzing the

results of Dr. Gitis's test report -- and specifically, the statistical analysis at the end of Dr. Gitis' test report which conclusively shows that the difference between coated and uncoated FiberWire sutures was "statistically significant." *See infra* at 3-5.

DePuy Mitek, however, does not stop there. It also asserts that since "Dr. Mukherjee cannot offer an opinion on whether FiberWire's coating affects its properties" -- a conclusion which DePuy Mitek reaches only by conscious and selective misrepresentation of the record -- Dr. Gitis' test report is inadmissible under FED. R. EVID. 403 since Dr. Gitis cannot explain the significance of his tests to the jury. But, DePuy Mitek is wrong on both the facts and the law.

Assuming for the sake of argument that Dr. Mukherjee could not explain the significance of Dr. Gitis' test results -- which he plainly can do -- Dr. Gitis still is allowed to explain his tests to the jury. Dr. Gitis' tests would be another piece of evidence to be considered by the fact finder in determining whether the coating added to FiberWire suture materially affects its pliability and/or handleability properties. The jury can hear the evidence, determine whether it stands up to DePuy Mitek's cross examination and decide how much weight it should be given. Moreover, it is simply too early to decide whether Dr. Gitis' tests should be excluded under Rule 403. A more appropriate time to weigh its admissibility is during trial.

II. DR. MUKHERJEE CAN EXPLAIN THE SIGNIFICANCE OF DR. GITIS' TEST RESULTS TO THE JURY

DePuy Mitek cites as the basis for its motion *in limine* portions of Dr. Mukherjee's deposition testimony that were taken completely out-of-context. For example, DePuy Mitek asserts that Dr. Mukherjee stated that he is not an expert in explaining the results of Dr. Gitis' data and how it relates to FiberWire's coating. Mitek Mem. at 5, 9. In another example, DePuy Mitek asserts that Dr. Mukherjee stated he could not answer whether the coating on FiberWire caused the knot slippage strength to increase or decrease based on the data reported in Table 2 of Dr. Gitis' test report. Mitek Mem. at 5. But, as Dr. Mukherjee repeatedly explained to DePuy

Mitek, he was not basing his expert opinions on the data points reported in the various tables of Dr. Gitis' report. Rather, *Dr. Mukherjee relied upon the statistical analysis of that data which Dr. Gitis presented at the end of his report at page 16* (at Table 7).

When DePuy Mitek questioned Dr. Mukherjee regarding specific data points, he explained that comparing two data points without conducting a statistical analysis is not the most appropriate way to judge test results. He explained that it is well known to conduct a statistical analysis on the average of the data points and the standard deviation of the data points. Ex. 2 at 438:2-7. He then explained that it was the statistical analysis of the data, as conducted by Dr. Gitis at the end of his report -- *and not some random data points to which DePuy Mitek pointed at his deposition* -- upon which Dr. Mukherjee relied in part in forming his opinions in this case.

For example, when Dr. Mukherjee was asked about the data points Dr. Gitis' recorded in Table 1 of his report in connection with his pliability tests, Dr. Mukherjee explained his reasoning as follows:

Q: See for sample number 2 of the coated, Dr. Gitis determined the stiffness was 7.53 times 10 to the minus 7th. Do you see that?

A: Yes, I do see.

Q: And for sample 6 of the uncoated he determined the stiffness was 8.00 times 10 to the minus 7th. Do you see that?

A: Yes.

Q: Are those two numbers statistically different?

A: [O]ne number you can't compare. *That's why the statistical analysis was done on the average and the standard deviation. That's the only way I know that you can make a judgment between the two groups of data.*

Ex. 2 at 435:15-436:10 [emphasis added]. Dr. Mukherjee went on to explain that conducting a statistical analysis is "*very common*" and "*nothing new.*" Ex. 2 at 438:2-7 [emphasis added].

In addition, when Dr. Mukherjee was asked about data points recorded in connection with Dr. Gitis' knot slippage strength testing, he explained the importance of the statistical analysis as follows:

Q: Sample number 1, the uncoated, failed at 4.09, and the coated failed at 3.06, right?

A: Knot failure? Yes.

Q: Okay. So the – sample number 1, the uncoated had a higher knot strength according to the test?

A: Again, *I cannot make any comments on individual data. Has to be the average and the statistical analysis of the data.*

Ex. 2 at 447:22-448:5 [emphasis added].

Further, when he was asked whether he had any opinions about coating's affects on the chatter of the suture, *based on table 5 (i.e., the data points recorded and not the statistical analysis at page 16 of Dr. Gitis' report)*, Dr. Mukherjee directed DePuy Mitek to the portion of Dr. Gitis' report that he did rely upon in part for his opinions. Specifically, he testified as follows:

Q: *Based on table 5*, did you have any – do you have any opinions about how the coating affects the chatter of a suture – of the FiberWire suture”

A: No, *but if you look at page 16, where the data were compared statistically, that's where I make my – I made my opinion.*

Ex. 2 at 456:21-457:1 [emphasis added].

In yet another example, when Dr. Mukherjee was asked *more globally* about Dr. Gitis' report, and the data points recorded in the report, he testified as follows:

Q: Dr. Mukherjee, for any of the data that was reported in Dr. Gitis' report, do you know why there was any variation between samples and the data?

A: Specifics, I cannot tell you, but I've done enough testing in my life, it does happen.

Q: Did you –

A: There are many – many explanations. Norm Gitis will be able to tell you that. *Again, I draw your attention to the – the table that I based my opinion on, expert opinion based on – on page 16. As an expert in analyzing data, I've done plenty, and I'm still doing those, that the – that statistically, there's significant difference from the coated and uncoated, and that is in my report.*

Ex. 2 at 465:5-20 [emphasis added].

Taken in the correct context, it becomes clear that Dr. Mukherjee was merely stating that he did not form any definitive opinions based on individual data points. Rather, Dr. Mukherjee was being a *careful and prudent* expert by insisting that he rely upon *the statistical analysis of the data* in forming his opinions.

DePuy Mitek's second broadside attack on Dr. Mukherjee, that he could not explain the methodological details of Dr. Gitis' tests, is a complete red herring. DePuy Mitek's epiphany should come as no surprise. After all, it is Dr. Gitis who is the testing expert. Dr. Mukherjee's testimony stands for nothing more than the unremarkable -- and correct -- proposition that the details of how the tests were conducted should be asked of the person in charge of the tests.

With this proper context in mind -- the context that DePuy Mitek avoids with surgical precision -- we now turn to the portions of Dr. Mukherjee's testimony relied upon by DePuy Mitek as the basis of its motion. DePuy Mitek points to Dr. Mukherjee's testimony in connection with several tests conducted by Dr. Gitis and asserts that Dr. Mukherjee "admitted either that he was not familiar with the test procedures used by CETR, or that he did not really have an opinion as to whether the coating had an effect on the tested [sic], or both." Mitek Mem. at 5. Neither charge has any basis.

DePuy Mitek first points to the knot slippage strength test and Dr. Mukherjee's testimony when he was asked if he had "an opinion whether the coating on FiberWire caused the knot strength to either increase or decrease *as reported in table 2.*" Mitek Mem. at 5. [Emphasis

added.] While DePuy Mitek tries to use this testimony to show that Dr. Mukherjee has no opinion, it forgets that its own citation proves *exactly the opposite*; that is, that Dr. Mukherjee used “the statistical analysis of these data” to render his opinions. Mitek Mem. at 5.

Similarly, in connection with the knot run down test (Mitek Mem. at 5-6), Dr. Mukherjee explained that he did not have an opinion as to whether the FiberWire coating affects the knot rundown “*based table 3*” (Mitek Mem. at 5, emphasis added). Table 3, like the other tables upon which DePuy Mitek relies in its motion, did not include the statistical analysis.

DePuy Mitek points next to the friction test and asserts that Dr. Mukherjee could not explain the results of that test and how it relates to FiberWire’s coating. Mitek Mem. at 6. But a closer look reveals that Dr. Mukherjee was responding to a question about friction test data points recorded at page 11 of Dr. Gitis’ report (in Table 4). For example, the portion of Dr. Mukherjee testimony that DePuy Mitek omitted went as follows:

Q: Okay. Is the friction test that he did, you see table 4, the friction test?

A: Page?

Q: Page 11 of the CETR report.

A: Okay.

Ex. 2 at 453:20-24. Thus, DePuy Mitek was *not* referring Dr. Mukherjee to the statistical analysis of the friction test data points (*i.e.*, at page 16, Table 7) upon which Dr. Mukherjee *did* rely, as shown above, *supra* at 3-5. But, rather, Dr. Mukherjee was only referring to individual data points.

DePuy Mitek also points to the chatter test as another test about which Dr. Mukherjee allegedly did not have any opinion. Mitek Mem. at 6. But, in “quoting” Dr. Mukherjee’s testimony, DePuy Mitek carefully dissects it so that the portion where he describes his reliance

on the statistical analysis at page 16 of Dr. Gitis's report is omitted. *Compare* Mitek Mem. at 6 and Ex. 2 at 456:21-457:14.

DePuy Mitek next points to Dr. Mukherjee's testimony in connection with the tissue drag test, but conveniently omits the facts that he was referring to the data points recorded at page 13 of Dr. Gitis' report and, once again, *not* to the statistical analysis of that data at page 16 (Table 7). Ex. 2 at 457:15-458:17.

Lastly, DePuy Mitek points to the pliability test and the portion of Dr. Mukherjee's testimony where he states that Dr. Gitis decided the procedure to be used. But, as explained above, Dr. Gitis is the testing expert, therefore, he selected the particular methods that were used. The testimony of Dr. Mukherjee upon which DePuy Mitek relies merely establishes the obvious -- the testing expert is the one who knows about the details of the selected test procedures. And once again, DePuy Mitek simply ignores Dr. Mukherjee's testimony where he explained that he relied on the statistical analysis of the averages of the data recorded during the pliability test. Ex. 2 at 435:12-436:10.

Although DePuy Mitek would have the Court believe that Dr. Mukherjee does not have any opinions regarding Dr. Gitis test report, as demonstrated above, the exact opposite is true. He clearly does have opinions that rely *not* on the data points recorded for each test, but rather, he relies upon *the statistical analysis of those data points*. That is precisely what a careful and prudent expert like Dr. Mukherjee should do. DePuy Mitek has it exactly backwards. Dr. Mukherjee should be lauded for his prudence and carefulness, not excluded.

Finally, even if there were any validity to DePuy Mitek's criticisms -- of which there is none -- the most that could be said is that DePuy Mitek can raise these questions in cross-examination. But DePuy Mitek's ill-conceived and misleading criticisms of Dr. Mukherjee do not come close to the showing necessary to exclude his testimony. *U.S. v. Mahone*, 453 F.3d 68,

72 (1st Cir. 2006) (“As long as an expert's scientific testimony rests upon good grounds, based on what is known, it should be tested by the adversary process -- competing expert testimony and active cross-examination -- rather than excluded from jurors’ scrutiny for fear that they will not grasp its complexities or satisfactorily weigh its inadequacies.”).

III. EVEN IF DR. MUKHERJEE COULD NOT EXPLAIN THE SIGNIFICANCE OF DR. GITIS’ TESTS, DR. GITIS CAN EXPLAIN HIS TESTS TO THE JURY

DePuy Mitek, without any authority, asserts that if somehow it were to convince the Court that Dr. Mukherjee was not able to explain the significance of Dr. Gitis’ findings, then Dr. Gitis’ tests are inadmissible under FED. R. EVID 403. DePuy Mitek concedes, as it must, that the test report is relevant to the issue of infringement. After all, Rule 403 governs the admissibility of *relevant* evidence. However, DePuy Mitek asserts that if Dr. Mukherjee cannot testify about Dr. Gitis’ tests, then no one else can. This makes no sense, because Dr. Gitis can surely describe his tests to the jury.

DePuy Mitek asserts a confusing and circular argument that to allow Dr. Gitis to testify about own tests would somehow unfairly prejudice DePuy Mitek. Mitek Mem. at 11. DePuy Mitek’s argument amounts to nothing more than “the jury may believe that Dr. Gitis’ tests help show why FiberWire suture does not infringe the ‘446 patent, and therefore should be excluded.”

But as this district has already stated; “‘Unfair prejudice’ described by Rule 403 does not refer to the fact that a particular piece of evidence will have an adverse effect on a party’s case. Most evidence offered by an opponent should have this impact. Rather, unfair prejudice within this context means an undue tendency to suggest [a] decision on an improper basis, commonly, though not necessarily, an emotional one.” *U.S. v. Buchanan*, 964 F.Supp. 533, 535 (D. Mass. March 31, 1997). Of course, Dr. Gitis’ tests, like the other evidence in the case,

should have an adverse impact on DePuy Mitek's case. That is not a reason for exclusion. The jury is entitled to review that evidence and weight it along with all of the other evidence in the case and to determine whether it stands up to DePuy Mitek's cross examination.

In any event, even if DePuy Mitek's concerns were valid -- which they are not -- it is premature at this point to decide whether Dr. Gitis' testimony regarding his tests is admissible under Rule 403. "Normally, the balancing process contemplated by that Rule is best undertaken at the trial itself." *Flebotte v. Dow Jones & Co., Inc.*, 2000 WL 35539238 at *6 (D. Mass. Dec. 6, 2000). Ex. 3.

IV. CONCLUSION

For the foregoing reasons, DePuy Mitek's motion should be denied.

Dated: July 24, 2007

Respectfully submitted,

By: /s/Charles W. Saber

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing DEFENDANTS ARTHREX, INC.'S AND PEARSALLS LTD.'S OPPOSITION TO PLAINTIFF DEPUY MITEK'S MOTION *IN LIMINE* (NO. 1) TO EXCLUDE EVIDENCE REGARDING CETR TESTING was served, via the Court's email notification system on the following counsel for Plaintiff on the 24th day of July 2007:

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Exhibit 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.)	
a Massachusetts Corporation)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 04-12457 PBS
)	
Arthrex, Inc.)	
a Delaware Corporation)	
)	
Defendant.)	

RESPONSIVE EXPERT REPORT OF DR. DEBI PRASAD MUKHERJEE
CONCERNING NON-INFRINGEMENT OF U.S. PATENT NO. 5,314,446
AND OTHER MATTERS

Pursuant to the provisions of Rule 26(a)(2) of the Federal Rules of Civil Procedure, the Joint Case Management Statement adopted by the Court on February 18, 2005, and agreement between the parties, the undersigned, Dr. Debi Prasad Mukherjee, an expert witness for Defendants Arthrex, Inc. and Pearsalls, Limited (together, "Defendants") hereby sets forth his responsive expert report concerning non-infringement and other matters as follows.

approximately 2-1/2 times easier to slide the knot down the suture.¹ In my opinion, these results demonstrate that coating materially affects knot tiedown of FiberWire suture.

In addition to the above described test, I have suggested tests of my own on coated and uncoated samples of FiberWire suture. Like the Arthrex test, the tests I suggested were objective in nature and also demonstrate that coating materially affects the handleability or pliability characteristics of FiberWire suture. The tests were conducted by the Center for Tribology in Campbell, California ("CETR"). The results are attached as Ex. 20. I understand that many of the world's leading suture manufacturing companies – including Ethicon and U.S. Surgical Corp. – use CETR to conduct various tests on their own suture.

Specifically, the tests conclusively show that the knot tie-down, chatter, coefficient of friction, knot security, pliability and tissue drag characteristics of FiberWire are each materially affected by the addition of coating. For example, the knot tie-down (knot run-down) test measures the force required to initiate movement of a half-hitch knot formed on the suture and also the force required to slide the knot down the suture. The results of the knot tie-down test are a function of the smoothness of the surface of the braid. The results of the knot tie-down test performed by CETR

¹ The mean peak force required to initiate slippage of the knot on the uncoated suture was 32.0N, whereas only 12.7N were required to initiate slippage of the knot on the coated suture.

demonstrate that approximately 1.8 times as much force was required to slide the knot on the uncoated FiberWire suture as compared with the coated FiberWire suture. Ex. 20 at 7-8.

The chatter and coefficient of friction tests are also measures of the smoothness of the braid surface and are also directly related to the knot tie-down test in that way. The more smooth the surface of the braid, the less force that is required to move the knot along the surface of the suture – this is a very desirable feature for surgeons working with surgical suture. Additionally, the more smooth the surface of the braid, the less chatter the knot will experience as it travels along the surface of the braid. The coating added to FiberWire smoothens out the “peaks” and “valleys” formed on the surface of the braid. As those peaks and valleys are smoothed, it becomes easier for the knot to move along the surface of the suture (i.e., less force is required to move the knot along the suture). The results of the coefficient of friction and chatter tests conducted by CETR are consistent with the knot tie-down test results. Specifically, the coefficient of friction for the uncoated FiberWire suture was approximately 1.8 times higher than that of the coated FiberWire suture. The chatter tests showed a similar differential between coated and uncoated FiberWire suture.

CETR’s test results also show that the addition of coating to FiberWire suture improves the suture’s pliability/bendability. Specifically, there was an approximately 63% difference in pliability/bendability for the coated and uncoated FiberWire samples,

demonstrating that the coating materially affects FiberWire's pliability/bendability. Ex. 20 at 3-4.

In addition, I conducted my own subjective "drape test" on samples of coated and uncoated FiberWire suture to determine the coating's effect on the pliability of the suture. The drape test involves draping the suture over my extended index finger and observing the degree to which the suture conforms to the shape of my finger. The results of my test showed that the coated FiberWire suture conformed to the shape of my index finger to a much greater degree than did the uncoated FiberWire suture, confirming that the coating materially affects FiberWire's pliability.

Further, Dr. Robert Burks performed a subjective tactile feel and knot tiedown analysis on coated and uncoated FiberWire suture. The results of his observations (Ex. 21) provide further support that the coating applied to FiberWire materially affects these handling properties. For example, Dr. Burks – not knowing which suture sample was coated and which was uncoated – consistently selected the coated sample as having better tactile feel as well as better tie-down performance.

Therefore, for the reasons explained above, it is my opinion the coating applied to the FiberWire suture materially affects the above-described handleability and pliability characteristics of FiberWire.

2. Coating materially affects FiberWire's knot security and knot strength

Dated: March 24, 2006

Debi P. Mukherjee
Debi Prasad Mukherjee, Sc/D.

Exhibit 2

0417

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS
Civil Action No. 04-12457 PBS

DEPUY MITEK, INC., a Massachusetts)
Corporation,)
Plaintiff,)
v.)
ARTHREX, INC., a Delaware Corporation)
Defendant.)

Videotaped Deposition of DEBI PRASAD MUKHERJEE

- VOLUME TWO -

Washington, DC

Wednesday, June 14, 2006

The videotaped deposition of DEBI PRASAD MUKHERJEE,
Volume Two, was held on Wednesday, June 14, 2006,
commencing at 9:12 a.m., at the offices of Dickstein
Shapiro Morin & Oshinsky LLP, 2101 L Street,
Northwest, Washington, DC, before Mary Ann Payonk,
RDR, Certified Realtime Reporter, Registered Diplomate
Reporter and Notary Public.

1 A You cannot --

2 MR. TAMBURO: Objection, vague, and
3 it's -- it's comparing two different samples so
4 it's -- it's irrelevant. But you can answer if you
5 know the answer.

6 A In addition to that, there are -- one
7 number, you can't compare. That's why the statistical
8 analysis was done on the average and the standard
9 deviation. That's the only way that I know that you
10 can make a judgment between the two group of data.

11 BY MR. BONELLA:

12 Q Well, I'm just talking about the
13 individual ones. Can you make any explanation as to
14 why the sample number 2 coated had 7.53, which was
15 relatively close to the uncoated sample number 6 of
16 8.0?

17 MR. TAMBURO: Same objection.

18 A Same thing. Sample-to-sample variation.

19 BY MR. BONELLA:

20 Q Sample-to-sample variation?

21 So you can't compare the results from
22 sample number 1 to sample number 8?

23 MR. TAMBURO: Same objection.

24 BY MR. BONELLA:

25 Q Is that what you're saying?

1 MR. TAMBURO: Same objection and
2 mischaracterizes the testimony.

3 A You cannot. Only thing you can compare is
4 the averages, and -- and that's what was compared
5 statistically.

6 BY MR. BONELLA:

7 Q You can only compare the averages?

8 A Yes.

9 Q Why statistically can you only compare
10 averages?

11 A Because of the reason that every sample
12 not the identical with the other. There will be a
13 variation whether the sample, the measuring procedure,
14 all these things. So that's why you always take the
15 average and you statistically analyze.

16 Q So it could be variations in the
17 procedures between the samples that affect the results
18 that it -- Dr. Gitis did in --

19 MR. TAMBURO: Object.

20 BY MR. BONELLA:

21 Q -- in table one?

22 MR. TAMBURO: Objection.

23 BY MR. BONELLA:

24 Q I'm sorry, in table one, yeah.

25 MR. TAMBURO: Objection, mischaracterizes

1 A Yes.

2 Q And your understanding is that 1.66 is the
3 standard deviation?

4 A For the uncoated suture.

5 Q Okay. Are you an expert in statistics?

6 MR. TAMBURO: Objection, vague.

7 A I use statistic but I'm not an expert --

8 BY MR. BONELLA:

9 Q Okay.

10 A -- in statistics.

11 Q Do you know statistically what -- can you
12 provide me a basis in statistics as to why an average
13 should be used to compare the samples as opposed to
14 some other statistical value?

15 A I don't understand your question.

16 Q Well, there's lots of different ways to
17 compare numbers in statistics. And you come up with
18 lots of different ways to compare them. And you --
19 you're saying that you must use an average, and I'm
20 asking you what is your basis in statistical knowledge
21 to say that?

22 A My knowledge -- you're asking what my
23 knowledge or asking of the statistical procedure --

24 Q Yes.

25 A -- that's normally used?

1 uncoated, had a higher knot strength according to that
2 test?

3 A Again, I cannot make any comments on
4 individual data. Has to be the average and the
5 statistical analysis of the data. And again, Norm
6 Gitis can explain these questions that you are asking
7 to me. I do not know the answer.

8 Q Can you explain why sample -- see sample
9 number 1? The uncoated -- uncoated has a higher value
10 than the coated. Do you see that?

11 A Yes.

12 Q For knot failure. See that?

13 A Sample number 1?

14 Q Right.

15 A Yes. The uncoated is higher than the
16 coated?

17 Q That's what the number looks like.

18 A Okay.

19 Q That number of 4.09 is higher than --

20 A I just want to make sure that's what
21 you're referring to.

22 Q Right.

23 A Okay?

24 Q Okay. Now, if you go down and you see
25 sample number 3.

1 A Yes.

2 Q Sample number 3, the coated number, is
3 3.15 at failure and the uncoated is 2.42. Do you see
4 that?

5 A Yes, I do.

6 Q So for sample number one, the uncoated
7 failed at a higher value -- value, and for sample
8 number 3, the coated failed at a higher value. See
9 that?

10 A I see.

11 Q How do you explain that?

12 A I answered your question over and over
13 again that I cannot answer the individual data. Norm
14 Gitis is the person who can explain this. I only can
15 see the averages. To my knowledge, that's the way to
16 look at it, not individual data like you're doing.

17 Q Okay. It -- it's your opinion -- is it
18 your opinion that the coating on FiberWire decreases
19 the knot strength?

20 MR. TAMBURRO: Objection, vague. Are we
21 going by the same definition of knot strength as
22 yesterday?

23 MR. BONELLA: The knot strength as
24 reported in table 2 of Dr. Gitis' report.

25 A I have to look at the statistical analysis

1 A Yes.

2 Q Okay. See how the coated had an average
3 of .09 and the uncoated had an average of 0.16? Do
4 you see that?

5 A Sample number -- which one you talking
6 about?

7 Q No, average.

8 A Average .009 and .014? Is that the one?

9 Q Sorry. I'm in the coefficient of
10 friction, table 4, test at the top.

11 A I will check it. Okay.

12 Q Okay? See how the coated had a average of
13 0.09?

14 A Right, yes.

15 Q And the uncoated had 0.16?

16 A Right.

17 Q Have you seen any data to put other data
18 of other sutures of what their coefficient of
19 frictions were?

20 MR. TAMBURRO: Objection, vague.

21 A I don't remember. I've seen my own eyes
22 working suture but not -- I don't remember.

23 BY MR. BONELLA:

24 Q Do you remember what values you saw in
25 your experience for coefficient of frictions for

1 I made my opinion.

2 If you look at the stiffness, all the
3 properties, coated and uncoated, differences, I -- I
4 just wanted to see whether different or not. And I
5 saw coated is different from uncoated. That much, I
6 did. But other than that, I haven't done anything
7 else. And Norm again who is the person to explain
8 more about the individual data point as well as
9 averages.

10 Q So you started by saying "no" to my
11 question, so do you have any opinions about how the
12 coating affects the chatter of a suture, of the
13 FiberWire suture?

14 A The answer is no.

15 Q Okay. Next test is a tissue drag test.
16 Do you know how that was performed?

17 A No.

18 Q Okay.

19 A Now, what page is that?

20 Q Page 12.

21 A Page 12.. Yeah.

22 Q Did -- have you seen any curves other than
23 what's shown in figure 13 for the tissue drag test
24 results?

25 A No.

1 Q In the drag force table, see the static
2 columns on the left?

3 A Yes.

4 Q On the left-hand side, sample number 1,
5 the coated suture had a static value drag force of
6 1.10. See that?

7 A Yes.

8 Q Number 5, sample number 5, uncoated, had a
9 value of 1.10. Do you see that?

10 A Yes.

11 Q Can you explain why sample number 1,
12 coated suture, and sample number 5, uncoated suture,
13 have the same static value of drag force?

14 A Again, Norm Gitis can explain. I cannot.

15 Q Do you have any opinions about how the
16 coating on FiberWire affects the drag force?

17 A No.

18 Q Next page is visual samples, pictures.

19 A Yes.

20 Q Page 14.

21 A Yes.

22 Q It shows four pictures on page 14. It
23 should be Exhibit C to your report.

24 A 14 and 15, yes.

25 Q See the four pictures?

1 A Yes.

2 Q Have you seen any other pictures of
3 FiberWire?

4 MR. TAMBURO: Ever?

5 MR. BONELLA: I'm sorry, I'll ask a better
6 question.

7 BY MR. BONELLA:

8 Q These pictures of FiberWire were taken
9 under scanning electron microscopy, is that right?

10 A Yes.

11 Q Okay. Were you present to visually look
12 at the FiberWire at that time when the pictures were
13 taken?

14 A No. None of this test I was present
15 there.

16 Q Okay. Did you see any other pictures that
17 were generated from the scanning electron microscopy?

18 A Yes, there was in the -- Dr. Brookstein's
19 report.

20 Q Okay. And other than the ones in
21 Dr. Brookstein reports, did you see any?

22 A No.

23 Q Okay. Have you seen any other pictures of
24 FiberWire at a magnification level done by any
25 procedure other than the ones in the CE -- CETR report

1 answered.

2 A You know, these are very specific
3 sample-related problem and -- and only Norm Gitis can
4 explain that.

5 BY MR. BONELLA:

6 Q Okay.

7 A Because I have not handled the samples.

8 Q You either know or you don't know. It's
9 either yes or no. Do you know of any reasons for the
10 variation in the sample -- individual sample results
11 that Dr. Gitis obtained for any samples?

12 A I do not know.

13 Q Okay. Did you ask Dr. Gitis for an
14 explanation for any variation in data between any
15 samples that he obtained?

16 A No. In my expert opinion, there is always
17 test variations, always. So I didn't ask him for
18 specific reasons because I know what they are mostly.

19 Q Okay. Did you determine the number of
20 samples that should be tested?

21 A I don't remember, but normally I do. And
22 Norm Gitis, he -- he probably knew what's the normal
23 number of samples we -- that tested for this purpose.

24 Q Okay. The question is yes or no. Did you
25 determine the number of samples that should be tested